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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,822	02/03/2000	Frank S French	5470-130DV	7943

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[REDACTED] EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
1646	[REDACTED]

DATE MAILED: 08/11/2003

*[Signature]*

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/497,822	<b>Applicant(s)</b> FRENCH ET AL.
	<b>Examiner</b> Michael Pak	<b>Art Unit</b> 1646

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 April 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 7,8 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) Claim(s) 8,10 and 12-17 is/are allowed.
- 6) Claim(s) 7 and 18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>18</u> | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Response to Amendment***

1. The amendments filed 2 December 2002 (Paper No. 20) and 16 April 2003 (Paper No. 22) and 25 September 2002 (Paper No. 17) have been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 25 September 2002 (Paper No. 17) have been fully considered but they are not found persuasive.
4. This application contains claim 11 drawn to an invention nonelected with traverse in Paper No. 14. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
5. The Declaration of Elizabeth M. Wilson under 37 CFR 1.132 filed 12 November 2002 (Paper No. 19) is noted. The Declaration discusses the discovery of sequence error and the changes to Sequences in the specification.

***Claim Rejections - 35 USC § 112***

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6. Claims 7 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The reason for the rejection was set forth in the last office action. Newly submitted claim 18 is dependent on claim 7. Claim 7 recite "DNA sequence encoding human androgen receptor" whose metes and bounds are not clear because no structure is provided in the claim limitation. Applicants argue that the specification contains two examples of androgen receptor sequence of human and rat. However, the claims are not drawn to specific sequence of human and rat androgen receptor but generically to "DNA sequence encoding human androgen receptor". The metes and bounds of the term "DNA sequence encoding human androgen receptor" is not clear because no structure is provided in the claim limitations.

7. Claims 7 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The reason for the rejection was set forth in the last office action. Newly submitted claim 18 is dependent on claim 7.

Claim 7 encompasses a "DNA sequence encoding human androgen receptor" which encompasses a variant and fragment of SEQ ID NO:19. However, the

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specification only discloses working example of a method of using specific species of androgen receptors which is the essential feature of the invention. *University of California v. Eli Lilly and Co.* (CAFC) 43 USPQ2d 1398 held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the disclosure does not have written description for the method of using a genus of variant androgen receptors. One skilled in the art cannot envision the sequence of the other homologs or orthologs of the SEQ ID NO:19 nor equivalent androgen receptors in other species of animals.

Applicants argue that the specification contains two examples of androgen receptor sequences of rat and human and one of skilled in the art would be able to isolate and purify a DNA sequence encoding human androgen receptor. However, the issue is not enablement but this is a written description rejection. The disclosure does not provide support for the generic claims of a "DNA sequence encoding human androgen receptor."

***Claim Rejections - 35 USC § 102***

8. Claims 7 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Liao et al. (US 5,614,620).

The reason for the rejection has been set forth in the previous office action. The newly submitted claim 18 is dependent on claim 18

Liao et al. disclose DNA encoding human androgen receptor (column 6, lines 49-60) and vector and host cell comprising the vector (column 3, 6, and 9).

Applicants argue that Liao et al. did not have the full length sequence in the priority application. However, the generic claim 7 does not exclude the androgen receptor of Liao et al.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 28 October 2002 (Paper No. 17) prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Claims 8, 10, and 12-17 are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 703-305-7038. The examiner can normally be reached on Monday-Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

*Michael D. Pak*  
Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
7 August 2003